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Report Highlights:

The United Kingdom (UK) is approaching the end of the transition phase of departure from the European Union (EU). On January 1, 2021, the UK will be responsible for risk assessing and approving new applications for products of genetic engineering. The UK has retained all EU regulation pertaining to cultivation of "Genetically Modified Organisms (GMOs)" and imports of "GMO" food and feed products. However, recent statements from Cabinet level politicians indicate a willingness to explore a more proportionate approach to regulation of products derived from simple genome editing.

Executive Summary

The UK formally left the EU on January 31, 2020. A transition phase began on February 1, 2020, during which EU law remains applicable to the UK. This is due to end on December 31, 2020. Following enactment of the Withdrawal Agreement Bill (on January 31, 2020), the UK converted directly applicable EU law into UK law. This is referred to as "EU retained law".

At the time of writing, the UK is nearing the end of the transition phase and no deal on future trading terms with the EU has been reached. The UK government has indicated that it has no plans to change the "Genetic Modification (GM)" regulations and approach to risk assessment that it has inherited from the EU. Secretary of State for Environment, Food, and Rural Affairs, George Eustice, recently said that when it came to conventional "genetic modification" – taking a gene from one plant or animal and putting it into another entity of an entirely difference genus – there were still ethical and food safety concerns.

However, the UK academic and scientific community has long-argued that the EU system for regulating genetically modified organisms is a 'process-based' approach that is less scientifically accurate than taking an 'evidence-based' approach. There is an ongoing UK stakeholder discussion about changing the definition of "Genetically Modified Organisms" (as it is currently defined under the UK's Environmental Protection Act 1990) to a definition that would exempt simple gene editing applications from the scope of "GM" regulation. A public comment period on gene editing is due to be launched before the end of 2020.

Academic research is the main focus of agricultural biotechnology in the UK, with no genetically engineered (GE) plants or animals in commercial production. However, the UK relies on imported GE feedstuffs (soybean and corn products) for the livestock sector. In addition, the UK's large food manufacturing sector uses products derived from genetically modified microbial applications for ingredients such as flavors, enzymes, and processing aids. Most mainstream grocery products do not contain GE ingredients that trigger labelling requirements.

Most of the UK public objects to cloning and GE animals on ethical grounds, and there are sensitivities relating to perceived animal welfare issues associated with the technologies. Opinions vary with the intended use, with medical applications (improved medicines) being the most accepted. The UK has imported embryo progeny of clones or embryos of clone progeny as well as bovine semen, which may have come from clones or their progeny.

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Reporting Notes:

1. The United Kingdom (UK) is a member of the European Union (EU) and this report should be read in conjunction with the Agricultural Biotechnology Annual European Union report available here: FAS/USDA GAIN Report Database
2. The term "agricultural biotechnology" refers to an evolving continuum of technologies. It is a broadly applied term that may or may not refer to crops developed through recombinant DNA technologies. Commonly used terms are: plant (or animal) biotechnology, transgenic, biotech, bioengineered, and genetically engineered (GE).
3. The U.S. government uses the term genetically engineered (GE) in addressing this topic. However, the EU legislation and Member State implementing regulations use Genetically Modified (GM) food and feed and Genetically Modified Organisms (GMO). These terms are used in quotes in this report when discussing EU legislation and UK implementation.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

The UK crop science community undertakes limited product development of genetically engineered plants. However, crop trials have increased in recent years:

Crop	**Research Facility**
Wheat (multi-trait)	Rothamsted Research [2017 and 2018]
Camelina (multi-trait)	Rothamsted Research [2014-2023]
Camelina (Omega-3)	Rothamsted Research [2014-2020]
Wheat (iron uptake)	The John Innes Centre [2019-2021]
Broccoli (sulfur flavor)	The John Innes Centre [2019-2021]
Potatoes (multi-trait)	The Sainsbury Laboratory and partners [2017-2021]

Innovative biotechnologies, such as CRISPR-Cas9, are now commonly used in UK research projects conducted by the key plant science research institutes listed above. In addition, the James Hutton Institute has recently completed work on barley using CRISPR.

b. COMMERCIAL PRODUCTION

Despite being a supporter of the science, the UK has never planted a commercial GE crop and has no crops under development. The limited portfolios of GE plant products that are approved for cultivation in the EU are not well-suited to UK growing conditions.

c. EXPORTS

The UK does not export genetically engineered crops or products to the United States or any other country.

d. IMPORTS

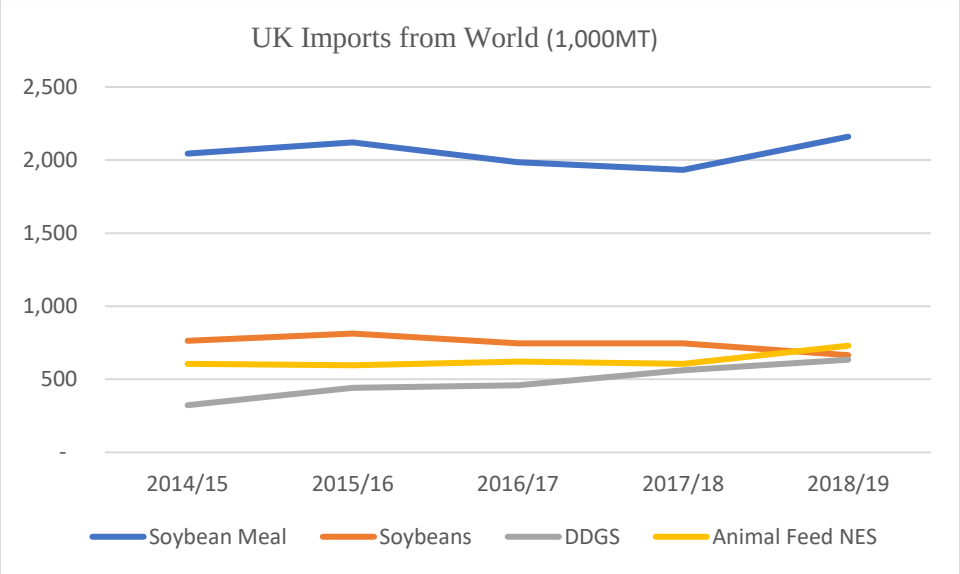
The UK is a protein-deficient market that needs to import grain and oilseed derivatives for livestock feed. Imports of animal feed products are influenced by animal stocking levels and domestic production of grains and oilseeds. The charts below show UK imports of animal feed commodities that are predominantly derived from GE crops, and those that the United States may export to the UK when conditions are favorable.

Confidence to purchase from a particular country is dependent on whether there is EU approval (for food and feed) for GE crops cultivated by the exporter. The main supplier countries are located outside of the EU and include Argentina, Brazil and the United States. Low Level Presence (LLP) of unapproved GE events in bulk shipments remains a concern that dominates trade decisions. The threshold for unapproved events found in animal feed is very low at 0.1 percent (and only for traits already in the EU approval pipeline). There continues to be zero tolerance for unapproved GE events found in food and seed.

Of course, trade is also dependent on many other things such as the fortunes of long-term supply chain investments for soybeans and soybean meal, availability of supply, demand, exchange rates, etc. The share of key commodities imported that are genetically engineered is estimated to be 80 – 90 percent.

Please see charts below for trade flows into the UK of the key GE commodities.

UK Imports from the World: Soybean Meal, Soybeans, Distiller's Dried Grains with Solubles (DDGS), and Animal Feed (not elsewhere specified)

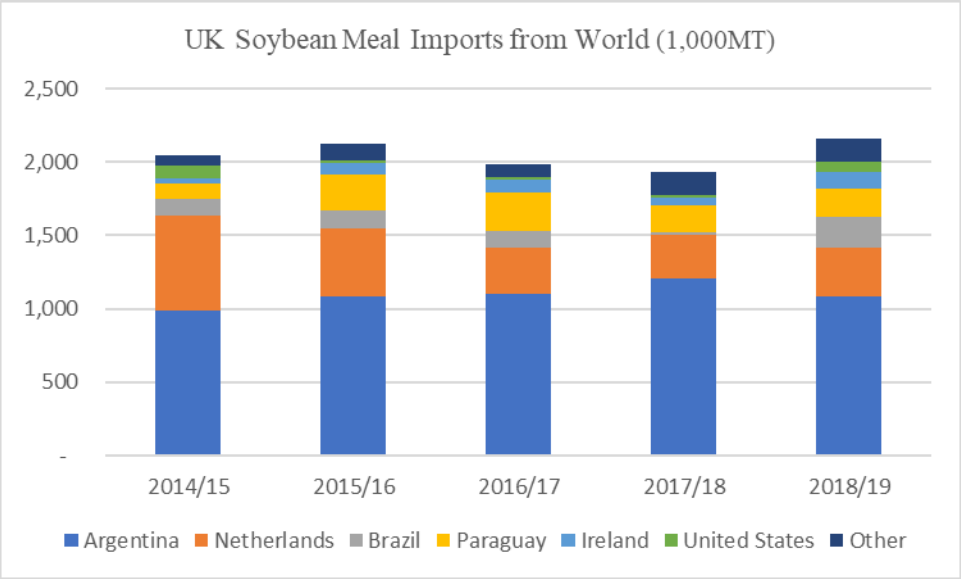


MT = metric tons; Marketing Years are October - September
Source: Trade Data Monitor/UK Data - Her Majesty's Revenue and Customs (HMRC)

The latest figures to August 2020 show an eight percent increase in soybean imports into the UK, a one percent increase in soybean meal imports, a 10 percent decline in miscellaneous animal feed, and a near thirteen percent decrease in DDGS imports. Notably, after years of steady growth, U.S. origin DDGS (from corn) imports have declined by 47 percent in 2020. The sharp drop in production of ethanol due to COVID-19, affected availability and pricing of DDGS.

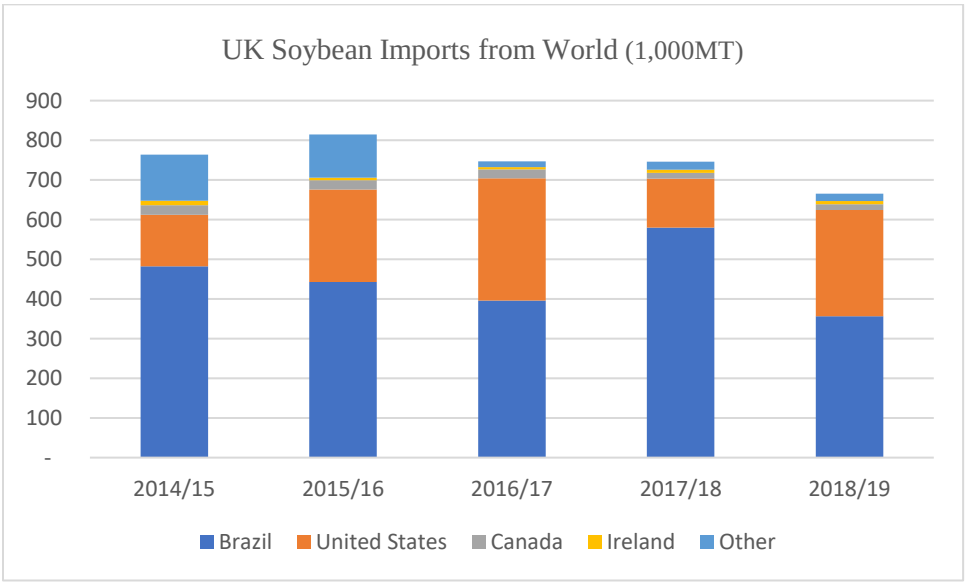
A significant volume of the key GE commodities is recorded as being imported from other EU destinations, particularly from the Netherlands port of Rotterdam. Ireland is also a key trans-shipment country for animal feed materials ultimately destined for the UK. This routing through other EU Member States makes it difficult to say definitively what proportion of UK imports can be attributed to the original country, such as the United States, Brazil, Argentina, etc. However, the vast majority of these commodities are from outside the EU as neither the Netherlands nor Ireland grows soy or corn in commercial quantities.

UK Imports from the World: Soybean Meal



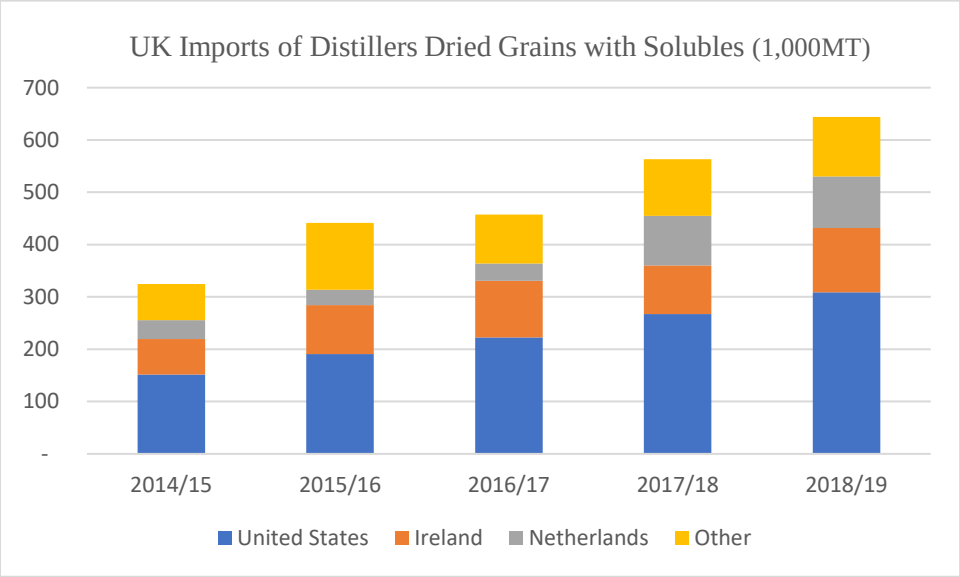
MT = metric tons; Marketing Years are October - September
Source: Trade Data Monitor/UK Data - Her Majesty's Revenue and Customs (HMRC)
Note: Supplies from Ireland are trans-shipments from other sources

UK Imports from the World: Soybeans



MT = metric tons; Marketing Years are October - September
Source: Trade Data Monitor/UK Data - Her Majesty's Revenue and Customs (HMRC)

UK Imports from the World: Distiller's Dried Grains with Solubles (DDGS)



MT = metric tons; Marketing Years are October - September
Source: Trade Data Monitor/UK Data - Her Majesty's Revenue and Customs (HMRC)

e. FOOD AID

The UK's Department for International Development (DFID) sends food packages, which do not include GE products, along with medical supplies to countries in need. The UK is not a recipient of food aid.

f. TRADE BARRIERS

For almost three decades, U.S. exports of processed foods and beverages have been constrained by market conditions and EU legislation pertaining to GE food products. As a result of a historically negative image of agricultural biotechnology, UK supermarkets and food manufacturers formulate their grocery products to exclude GE ingredients. Usually, the GE element of processed foods is a small component of the overall product, for example, soy lecithin (used as an emulsifier). This means that the additional cost of sourcing non-GE ingredients adds only a small contribution to the finished price of the goods. However, for many U.S. companies, the additional burden to source non-GE ingredients to supply the EU is often too large a hurdle to overcome. This is also increasingly the case for other countries wishing to supply the EU. As approximately 30 countries now produce GE crops it is becoming ever-harder to source non-GE ingredients. Private standards are increasingly affecting the incorporation of GE feed into animal feed rations. Depending on the product line, high end grocery chains may make it a condition of supply that the animals have been fed a non-GE diet.

PART B: PLANT BIOTECHNOLOGY POLICY

a. REGULATORY FRAMEWORK

The UK departed the EU on January 31, 2020. From that date, the UK adopted all relevant EU Directives and Regulations including novel foods and processes into a body of "retained EU law" that is now domestic law. At the time of writing, the UK is still in transition phase (ends December 31, 2020) of its EU departure, and the terms of future regulatory alignment and trade is not fully clear.

The key new UK regulation that remove references to EU institutions and clarify UK sovereignty is:
The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019
This is an amendment to:
Genetically Modified Organisms (Deliberate Release) Regulations 2002

The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019
Amend: The Genetically Modified Food (England) Regulations 2004

The UK's Withdrawal Agreement with the EU means that Northern Ireland will stay aligned with many EU rules on goods after the transition ends, but the UK government is not likely to commit to alignment for the rest of the UK.

A further relevant Statutory Instrument that has not been amended is:
The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004 Similar regulations covering all of the above legal texts have been made for Scotland, Wales, and Northern Ireland.

Responsible UK authorities

1. The Health and Safety Executive (HSE) regulates genetically modified organisms ("GMOs") in contained use (e.g., in a laboratory). Link to HSE

2. The Department for Environment, Food & Rural Affairs (Defra) is responsible for the control of the deliberate release of GE agricultural products and for national and international policy on the environmental safety of such products. Link to Defra, see Appendix 7, the term used is "GM."

   Defra is the competent authority that implements and enforces the content of the retained Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GE agricultural products genetically modified organisms. Link to EU Directive 2001/18/EC

   Defra provides the secretariat for the Advisory Committee on Releases to the Environment (ACRE). ACRE is an independent advisory body that reviews applications for field trials of GE agricultural products. Link to Defra/ACRE

3. The Food Standards Agency (FSA) controls the assessment of GE food for human consumption (food and feed), and consumer labeling of GE foods. Link to FSA, term used is "GM."

The FSA is advised on both GE and novel foods by an independent body of experts called the Advisory Committee on Novel Foods and Processes (ACNFP) and on GE animal feed by the Advisory Committee on Animal Feedingstuffs (ACAF). The ACNFP is responsible for assessing the safety of novel and GE food, and ACAF is responsible for assessing the safety of GE feed.

The United Kingdom is comprised of England, Wales, Scotland and Northern Ireland. The devolved governments of Wales, Scotland, and Northern Ireland have jurisdiction over agriculture, fisheries, and food policy in their regions. These countries have a higher proportion of "Less Favored Areas" (difficult to farm landscapes) for agriculture under EU Common Agricultural Policy definitions than England, and they trade heavily on their 'pristine and natural environment' image.

In 2015, Wales, Scotland and Northern Ireland notified the European Commission that they wished to "opt-out" of cultivation of GE crops. The EU directive allowed Member States to ban the cultivation of GE plants in their respective territories for non-scientific reasons (see more information on the "opt-out" here). These more rural communities generally believe that growing GE crops may damage the reputation of their produce, and as such, this outweighs any benefits that agricultural biotechnology might bring.

In formulating overall UK agricultural biotechnology policy, the central government (based in London) solicits views from a wide range of stakeholders, including the devolved Parliaments.

b. APPROVALS

From January 1, 2021, the UK will operate and manage its own approval system for GE products, continuing to distinguish between approval for food, feed, processing, or environmental release following the approach laid out in EU retained law [Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003]. In the meantime, approvals can still be progressed through the EU approval process (please see Agricultural Biotechnology Annual European Union report in the: FAS/USDA GAIN Report Database) The UK may recognize and transfer the status of any EU application, depending on how far it has progressed through the approval system. According to the FSA, it is finalizing procedures for (food and feed) applications submitted to the EU before the end of the transition period for which the assessment process has not been completed, and it will provide guidance in due course. See more at: Regulated Product Authorisation Application

c. STACKED or PYRAMIDED EVENT APPROVALS

The approval process for stacked events is similar to that for single events. For import or cultivation into the UK, these types of GE events must also apply through the EU legislation and approvals system for stacked or pyramided events until December 31, 2020. Further information on the EU approval process can be found here: European Food Safety Authority, and Page 8 of EFSA Guidance for Risk Assessment. Also, for more information, please see Agricultural Biotechnology Annual European Union report at: FAS/USDA GAIN Report Database.

d. FIELD TESTING

Defra is the lead agency for authorizing and overseeing field testing. However, the devolved administrations of Scotland, Wales, and Northern Ireland have powers over cultivation on their territory.

An application for a field trial is made to Defra under Part B of the EU retained law (Reference: Deliberate Release Directive (2001/18/EEC), which covers release for research and development.

Over 70 GE crop trials have been conducted in the UK since 2000, mainly on corn, sugar beet, oilseed rape, wheat and potatoes. See section a) Product Development for further information on current field trials.

e. INNOVATIVE BIOTECHNOLOGIES

Innovative biotechnologies include CRISPR-Cas9, oligonucleotide-directed mutagenesis (ODM), zinc finger nuclease (ZFN), cisgenesis and intragenesis, grafting, agro-infiltration, RNA dependent DNA methylation, reverse breeding and synthetic genomics.

The European Court of Justice ruled in 2018 that organisms obtained by mutagenesis and through genome editing were "GMOs" and therefore fell within the scope of the EU's Deliberate Release Directive 2001. Consistently since, and again most recently in June 2020, Secretary of State George Eustice said, "*the UK disagreed with the judgment of the European Court of Justice on this, in that we think that gene editing techniques such as CRISPR and other similar ones are really a more targeted form of conventional breeding in that it is cis-genesis.*"

A public comment period on how to regulate genome edited products is due to be released by the UK government before the end of 2020.

f. COEXISTENCE

The UK currently does not have a policy. The basis for any UK coexistence policy is likely to be the extensive work carried out and published by the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) in 2006. Information on their proposals for coexistence and liability can be found here: SCIMAC

The UK government's policy on coexistence of GE crops with conventional or organic crops states: "*If and when genetically modified crops are grown in England commercially, we will implement pragmatic and proportionate measures to segregate these from conventional and organic crops, so that choice can be exercised and economic interests appropriately protected.*"

g. LABELING AND TRACEABILITY

For consumer-ready grocery products, labeling is triggered by intentional inclusion in a product and if there is accidental presence of 0.9 percent or more approved "GM" ingredients as a percentage of the individual ingredient. The list of ingredients should contain a reference, for example: "contains soya oil from genetically modified soya." More at: GMO Traceability and Labelling (England) Regulations (similar regulations exist in all UK regions).

Guidance on labeling GE products, ingredients or processing aids can be found here: Food Standards Agency "GM" Labelling

Seed Labeling Legislation

In the absence of any EU seed labeling regulation for the adventitious presence of GE seed, the European Commission has advised (and therefore the UK currently follows this advice) that any seed lot containing "GM" seed authorized for the cultivation has to be labeled as containing "GMOs." Seed lots containing GE seeds that are not authorized for cultivation cannot be marketed in the EU/UK. In the UK, this is enforced by the "GM" Inspectorate of the Animal and Plant Health Agency (APHA GM Inspectorate).

h. MONITORING AND TESTING

All UK imports are subject to random or more frequent testing (depending on product) upon border entry. Since it is not a food safety concern, testing for genetically enhanced material is normally randomized testing. Until the end of 2020, the UK will have access to the EU Rapid Alert System (RASFF) and may invoke additional testing if a particular product and origin is flagged as problematic. At the time of writing, it is not clear whether the UK will continue to have access to the RASFF system once transition phase of departure from the EU is complete. The food supply chain conducts its own testing to satisfy import specifications, labeling obligations, and customer assurance.

i. LOW LEVEL PRESENCE (LLP) POLICY

The EU, and therefore the UK, has a zero-tolerance policy for low-level presence of GE products in food and feed. The EU's authorization procedures for new agricultural biotechnology varieties tend to be slower than those of other countries, a time-lag known as 'asynchronous authorization' occurs. To deal with the possible presence of unauthorized varieties in imports of feed commodities, the EU published (and the UK has adopted) Regulation 619/2011, which defines "zero" with a "technical solution" level 0.1 percent for GE varieties that have a valid application for an EU authorization has been made and that fulfil the requirements set out in Article 2 of the Regulation. There is no set technical solution for food or seed. Above this threshold, the product is not allowed on the EU/UK market. Operators must demonstrate that the presence of "GM" material was adventitious or technically unavoidable.

j. ADDITIONAL REGULATORY REQUIREMENTS

The UK has no additional regulatory requirements.

k. INTELLECTUAL PROPERTY RIGHTS (IPR)

The UK has a comprehensive system to address Intellectual Property Rights, including an Intellectual Property Office (IPO) that covers plant breeders' rights. A patent can be granted at a national level through the IPO.

The Animal and Plant Health Agency (APHA) takes the lead on plant intellectual property and plant variety rights. See: Guidance on Plant Breeders' Rights

l. CARTAGENA PROTOCOL RATIFICATION

The UK is a signatory to the United Nations' Convention on Biological Diversity, and has ratified the Cartagena Protocol on Biosafety. Defra is the contact point.

England implemented EU Council Regulation EC No. 1946/2003 by way of the *Genetically Modified Organisms (Trans-boundary Movements) (England) Regulations* 2004. Similar regulations have been implemented in Scotland, Northern Ireland and Wales. These regulations establish a common system of notification and information for transboundary movements of GE organisms and ensures coherent implementation of the provisions of the Cartagena Protocol on Biosafety.

m. INTERNATIONAL TREATIES/FORUMS

The UK is an active participant in all major plant health and international regulatory forums including the International Plant Protection Convention (IPPC), European Plant Protection Organization (EPPO), Food and Agriculture Organization of the United Nations (FAO), World Trade Organisation (WTO), Codex Alimentarius, and the Organization for Economic Cooperation and Development (OECD). In all forums, the UK consistently takes a pragmatic position based on evidence and science-based risk assessment.

n. RELATED ISSUES

There are no related issues.

PART C: PLANT BIOTECHNOLOGY MARKETING

a. PUBLIC/PRIVATE OPINIONS

The UK has several academics that are vocal on both sides of the debate. Most are proponents of responsible use of biotechnology. The Science Media Centre plays a role in fielding relevant experts to speak publicly following requests from journalists for specialist information and comment.

There are many organizations actively campaigning against the technologies, including but not limited to GeneWatch, GM Freeze, Friends of the Earth, the Soil Association, and Royal Society for the Protection of Birds.

For most of the British public, genetic engineering in food is irrelevant. There are very few mainstream grocery products that clearly contain GE ingredients. With this invisibility, UK consumers consider the "GM problem" to have gone away.

For those who distrust the technology or have limited knowledge and hold only a sense or a feeling on the subject, many cite the concentration of power over staple food crops by big business as their main concern.

b. MARKET ACCEPTANCE/STUDIES

Over recent years there has been positive media coverage that sets agricultural biotechnology in the context of its potential to support global food security, while addressing climate change, and feeding a

burgeoning global population. However, this has never translated into general acceptance for the presence of GE ingredients in the UK food supply.

"Choice editing" by retailers or foodservice companies determines what is sourced by the supply chain. Due to the zero-tolerance for un-declared GE material in food, the food manufacture sector actively avoids and substitutes GE ingredients.

The existence of GE crops in the global marketplace has negatively affected imports of food products containing soy and corn-based products. In addition, products containing glucose or other sugar components of GE sugar beet, sugar cane, or oilseed rape (Canola) must be labeled, and by doing so the GE presence is highlighted. Some supply chains may decide that they do not want GE ingredients/labeled products as the product may not be listed or carried in UK inventories. However, there are a few examples of products overcoming the hurdles, labeling appropriately and achieving sales success. These products are usually those where consumers have a desire for the product or there is a price incentive that counters the presence of GE ingredients, for example, "cult" confectionery, candy bars and low-cost cooking oils.

Innovative biotechnologies may have a smoother path to consumer acceptance. This will depend on the nature and purpose of the change that is created, and how any consumer benefits are communicated.

In the animal feed sector, the majority of soybean, and corn derived feeds are genetically engineered. There is much less sensitivity about feeding GE feed to animals, as finished meat, dairy, and poultry products do not need to be labeled, and there is no genetically-altered material in the final product. Organic options are available in the market for those who wish to avoid GE-fed livestock products, and the up-scale Waitrose chain (capitalizing on the opportunity to differentiate from its competitors) now states that "No Waitrose food is genetically modified". See more here: Waitrose policy statement Waitrose has five percent of the grocery retail market, and organic sales are approximately 1.5 percent of the overall food and drink market.

Marketing Studies

There have been many consumer attitude studies conducted over the last two decades. The identity of the entities that paid for the research tends to influence the acceptance of the data. In general, it is possible to say that over time there has been movement towards greater understanding of the benefits that genetic engineering can bring. However, a Countryfile Live poll in 2019 found that shoppers are still largely resistant to knowingly purchasing foods that contain GE ingredients. It is interesting to note that a 2018 Populus poll (carried out for the Agricultural Biotechnology Council), of more than 1,600, 18 to 30 year olds, found that only 20 percent of millennials expressed concerns about gene editing or genetically engineering crops. In addition, it found that two-thirds of under-30s believe technology is a good thing for farming and support futuristic farming techniques.

In 2016, a survey of 2,000 Brits, carried out by Populus for the agrochemical company Bayer Crop Science, found that two thirds of respondents said that they would support GE food so long as it did not harm public health or the environment. Fifty-four percent said that they agreed with GE crops in principle and a further 10 per cent said they were the only way to feed a growing global population. Twenty-seven percent said that they were opposed to biotechnology outright.

Consumer views are in stark contrast to those of UK farmers. According to a poll by industry magazine Farmers Guardian in 2019, more than three quarters of farmers say they would adopt GE crops if regulations changed.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

Research is the focus for animal biotechnology in the UK. Genus (an animal genetic improvement company) and Tropic Biosciences (an agricultural biotechnology company) have announced a collaboration to explore the application of Tropic's Gene Editing induced Gene Silencing (GEiGS) technology in porcine and bovine genetics.

No UK cloning research is currently taking place that will result in live farm animals. Genetically Engineered animals, such as those below, are under development but none are expected to be on the market in the UK within the next five years.

Event	**Organization**
GE mosquitoes to control dengue fever, malaria	Oxitec/Intrexon
GE olive fly, medfly, bollworm	Oxitec/Intrexon
GE pest insects	Pirbright Institute
GE insects	Beta Bugs
Suppression of avian influenza transmission in GE chickens	Roslin Institute
Gene-edited (ZFNs and TALENS) Pig 26 (for biomedical research)	Roslin Institute

b. COMMERCIAL PRODUCTION

Genetically Engineered animals (particularly mice, some rats) and fish are produced in the UK for research purposes. Mice and rats are used in the safety testing of some chemicals and medicines, while fish genetic engineering is mainly for breeding purposes.

In addition, GE invertebrates such as fruit flies and nematode worms are widely used by UK researchers. With regards to products from animal biotechnologies, embryo progeny of clones or embryos of clone progeny have been imported for use in the dairy sector. Bovine semen is also

imported, including from U.S. Holstein herds, so it is possible that this has been sourced from clones or their progeny.

c. EXPORTS

The UK exports GE mosquito eggs for development and subsequent release in countries where Oxitec has received approval for it GE insects e.g. Brazil and the Cayman Islands. Apart from these, the UK does not export GE animals, livestock clones, or products from these animals. It is possible that the UK exports products produced from, and genetics from, the progeny or subsequent generations of clones.

d. IMPORTS

As mentioned above, the UK has imported embryo progeny of clones or embryos of clone progeny as well as bovine semen which may have come from clones or their progeny. No import data is available as these products are not differentiated from other embryos or semen. The UK has not imported live GE animals or livestock clones.

e. TRADE BARRIERS

Ethical and welfare concerns exist, but there are no known physical trade barriers in the UK.

PART E: POLICY

a. REGULATORY FRAMEWORK

As with plant biotechnologies, the UK Government takes a pro-science and generally positive, pragmatic and progressive approach to animal biotechnologies. At present, the UK does not have any country specific legislation or registration requirements on animal biotechnology; it is currently following the EU legislation that it has inherited in this area until such time as it may or may not choose to deviate.

Please see FAS USDA's Agricultural Biotechnology Annual European Union report for more information on the EU regulatory framework in the FAS/USDA GAIN Report Database

The Department for Environment, Food, and Rural Affairs (Defra) plays an overarching role in the implementation of animal biotechnology regulation in the UK. The Health and Safety Executive helps to control the contained use of genetically engineered organisms in the UK to ensure no products or animals are released or exposed to humans without safety inspections and approvals. Further information on Defra's role in the regulation of GE animals and/or livestock clones, is available here

The Farm Animal Genetic Resources Committee (FAnGR) gives advice to the UK government on issues to do with farm animal genetics. See: FAnGR

b. INNOVATIVE BIOTECHNOLOGIES

As covered in the PART A a) - Product Development section above, UK researchers are using innovative biotechnologies in research applications.

It is not often covered by mainstream media, but UK stakeholders are still engaged in an ethical debate about the significance of the distinction between changing the characteristic genomes of species over

time through selection, and making changes by use of molecular techniques to directly alter farmed animal genomes. An inquiry by the Nuffield Council for Bioethics launched in 2019 is due to conclude and report at the end of 2020.

c. LABELING AND TRACEABILITY

Guidance on labeling GE products, ingredients, or processing aids derived from GE animals or clones can be found here: Food Standards Agency "GM" Labelling

d. INTELLECTUAL PROPERTY RIGHTS (IPR)

The UK has a comprehensive system to address Intellectual Property Rights, including an Intellectual Property Office (IPO) that covers animal breeders' rights. A patent can be granted at a national level through the IPO or through the European Patent Office. See: Guidelines for Patent Applications relating to Biotechnological Inventions

e. INTERNATIONAL TREATIES AND FORUMS

The UK is a very active participant in international forums, and can generally be relied upon to be a pragmatic and proportionate regulator. The UK is a member of Codex Alimentarius and the direct liaison point is Defra: codex@defra.gsi.gov.uk.

As regards the World Organization for Animal Health (OIE), Defra is the liaison point for Great Britain (England, Scotland, Wales) and the Department of Agriculture, Environment and Rural Affairs (DAERA) represents Northern Ireland in that forum.

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS

The UK has several organizations, such as the Biotechnology and Biological Science Research Council (BBSRC) and the Roslin Institute, active in public, positive engagement on animal biotechnologies. There are also many organizations actively campaigning against the technologies, including but not limited to GM Freeze, GeneWatch, Friends of the Earth, the Soil Association, the Royal Society for the Prevention of Cruelty to Animals, and Compassion in World Farming (CIWF).

The UK population has a generally low understanding of the science behind the technologies. Many object to cloning and GE animals on ethical grounds, and there are sensitivities relating to perceived animal welfare issues associated with the technologies. Opinions vary with the intended use, with medical applications (improved medicines) being the most accepted. If consumers' level of awareness regarding the positive animal welfare traits were higher (such as the example of breeding cattle without horns so that they do not have to be de-horned) then it could be expected that this would increase the acceptance of the technologies. However, some animal rights supporters oppose any intervention, even new welfare-friendly practices, as animals have no say.

Publicly funded research is more trusted than that undertaken by the private sector. There is a positive bias towards technology provided for free as a public good compared to that perceived to be created for financial reward by private companies.

b. MARKET ACCEPTANCE/STUDIES

No independent market research has been undertaken that provides statistics on the potential acceptance of marketing farmed animal biotechnologies in the UK.

The Animal Welfare Committee (AWC) is an expert committee of Defra (previously Farm Animal Welfare Committee – FAWC). It provides advice to Defra on the welfare of animals, including farmed animals on agricultural land, at market, in transit and at the place of killing. In November 2012, the Committee published its "Opinion on the welfare implications of breeding and breeding techniques in commercial livestock agriculture." The detailed report is available here. Among its many conclusions, it is notable that it encourages publicly funded animal biotechnology researchers to "engage closely with the livestock breeding industries to target the research effort better towards traits that are likely to have the greatest impact on animal welfare." Historic FAWC reports and advice provided to the UK government can be found here: FAWC publications

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a. COMMERCIAL PRODUCTION

The UK produces food ingredients derived from microbial biotechnology. The domestic food industry receives much of its biotech microbes from China, as well as from multi-national companies based in the United States, Denmark, Germany, and the Netherlands.

Examples of UK products manufactured using enzymes or other processing aids from biotech microbes include:

Product	**Company**	**Process**
Allulose (Sugar Substitute)	Tate & Lyle	Corn‣Starch‣Fructose‣Allulose using biotech microbe derived enzyme
Nootkatone (Flavor and Scent of Grapefruit)	Oxford Biotrans	Oranges‣Valencene‣Nootkatone using P450 biotech derived enzyme
Animal-free milk proteins	Better Dairy	Synthetic biology and yeast fermentation to produce dairy products without cows
Algae for protein needs	Algenuity	Unilever and Algenuity partner to develop microalgae for plant-based foods
Omega-3 rich micro-algae	MiAlgae	Food and drink industry by-products are processed to replace marine ingredients in fish feed
Abunda proteins	3F Bio (spin out from University of Strathclyde)	Mycoprotein made using zero waste fermentation process from sugar, for use as food, ingredients, and pet food

The UK has a number of venture capital firms tailored to support food application biotechnology. For example: RebelBio and Startupbootcamp Food Tech. The U.S. has by far the most venture capitalists in this space, but China and the UK are also active in this arena.

An example of a British company that produces specialist microbes using genetic engineering is: Biocatalysts - developing and manufacturing specialty enzymes in small to large scale quantities for a variety of industries, such as food, flavour, fragrance, life science, pharma, and fine chemicals. Biocatalysts offer a rapid, low-cost specialty enzyme service from discovery phase through to global shipment of regulatory compliant enzymes.

b. EXPORTS

There are no official statistics or estimates on exports of microbial biotechnology products. However, trade is likely to be substantial as the UK exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

c. IMPORTS

There are no official statistics or estimates on imports of microbial biotechnology products. However, given the significant size of the UK's food manufacturing sector, imports are likely to be considerable. Enzymes, flavorings, colors, etc., and the related final food ingredients, which derive from microbial biotech, are imported by the UK and are used throughout every food manufacturing sector e.g. alcoholic beverages, dairy products, bakery products, and other processed products. The UK also routinely imports finished alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

d. TRADE BARRIERS

Besides trade barriers described in the GE plants chapter of this report, there are no known additional biotechnology-related trade barriers that negatively affect U.S. exports of microbial biotech-derived food ingredients or processed food products containing microbial biotech-derived food ingredients.

PART H: POLICY

a. REGULATORY FRAMEWORK

The primary UK government department responsible for microbial biotechnology is the Health and Safety Executive (HSE). However, Defra may also have oversight if deliberate release to the environment is involved.

The Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU)) is a non-statutory scientific advisory committee established in 2004. SACGM(CU) provides scientific advice to the competent authorities on the contained use of 'GMOs', particularly in respect of hazard identification and risk assessment.

The regulation of microbial biotechnology is governed by:

the Genetically Modified Organisms (Contained Use) Regulations 2014.

These regulations transpose and implement European Council Directive 2009/41/EC on the contained use of genetically modified microorganisms.
Guidance on the contained use regulations is available here:
https://www.hse.gov.uk/pubns/priced/l29.pdf.

The regulation listed above sets out the duties of the person responsible to ensure that contained use involving genetically modified microbes (GMMs) is assessed before any work starts and that any relevant risks are identified and controls assigned. These include risks (whether immediate or delayed) to the health of humans and the environment, arising from the contained use of "GMMs." Following the risk assessment process (laid out in the regulations), a notification of contained use must be sent together with operator address details to the HSE. The responsible person must also have in place containment and control measures, and emergency plans.

There are no known pending UK regulatory developments that have the potential to affect U.S. exports.

b. APPROVALS

The UK does not collate information on biotech microbes and/or derived food ingredients approved or registered for use, import, and export. Similarly, there is no public information available on techniques used to alter microbes. This is commercially held and sensitive information.

The HSE maintains a public register of notifications indicating contained use of "GMOs" here: https://www.hse.gov.uk/biosafety/gmo/notifications/publicregister.pdf However, this public register is mostly biomedical research and probably less than one percent food and agriculture-related activity.

c. LABELING AND TRACEABILITY

The UK adopted all pertinent EU law in this subject into its own regulations. See Chapter 1, Part B, Section g. There are no known plans to revisit this element post-EU departure.

Products that are not legally defined as ingredients according to Article 6.4 of Directive 2000/13/EC, such as processing aids (like food enzymes produced from GE microorganisms) are exempt from labeling obligations.

d. MONITORING AND TESTING

Since January 31, 2020, the UK has adopted all pertinent EU law in this subject into its own regulations. See Chapter 1, Part B, Section h. There are no known plans to revisit this element post-EU departure.

The UK enforces mandatory monitoring plans for environmental effects and for use as food or feed. However, biotech microbes fall outside of monitoring and testing requirements since they are usually filtered out before final product is achieved.

e. ADDITIONAL REGULATORY REQUIREMENTS

There are no known additional biotechnology-related regulatory requirements that negatively impact U.S. exports of microbial biotech-derived food ingredients.

f. INTELLECTUAL PROPERTY RIGHTS (IPR)

Microbial biotechnology is covered under the same rights and laws as GE plants and animals. Please see Chapter 1, Part B, Section k.

g. RELATED ISSUES

None

PART I: MARKETING

a. PUBLIC/PRIVATE OPINIONS

Microbial biotechnology has never been high on the political agenda, and there is currently no high-profile lobbying for or against its use in food. In general, the public is not aware that microbial biotechnology is an essential part of today's food production. There is also very limited media coverage of the issue.

b. MARKET ACCEPTANCE/STUDIES

There is little to no awareness of microbial biotechnology in food production by the British public.

Attachments:

No Attachments